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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,758	03/12/2002	Helmut Wittler	50733	2769

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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/070,758

Applicant(s)

WITTELER ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Examiner acknowledges receipt of request for reconsideration, remarks and declaration under rule 1.132, all filed 1/25/07. Claims 1-9 and 12-20 are pending.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9 and 12-20 remain rejected under 35 U.S.C. 102(b) as being anticipated by Denzinger et al. (US 4,402,937).

Denzinger discloses a process for preparing polyvinylpyrrolidone (PVP)-iodine by reacting the PVP with elemental iodine in the presence of formic acid, oxalic acid, or ammonium salt or amide of carbonic acid, formic acid or oxalic acid and the reaction is carried out in aqueous solution (abstract and column 3, lines 1 and 2). The preparation starts with an aqueous solution of PVP of from 10-60% (column 4, lines 33-37), the PVP has a K value of from 8-50 (column 3, lines 37-41). In example 1, iodine is in an amount of 6% based on the weight of PVP and an available amount of 4.1%. The available iodine in example 2 is 5.1% and 6.2% in example 3. The mixture of the PVP and iodine and formic acid is heated at 70 °C for 20 hours (example 1), at 80 °C for 5 hours (example 2) and at 75 °C for 2 hours and a solid product is isolated from the aqueous solution by drying, spray drying or spray granulation (column 4, lines 53-56). See also claims 1-3. Instant claim 12 is a composition claim and future intended use is

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not critical in a composition claim. Formic acid is a reducing agent of the instant claims. The examples are exemplifications illustrating some aspects of the disclosed process and do not cover all possible combinations of the range of K-values of PVP solutions and the concentrations of the PVP-solution. Denzinger meets the limitations of the instant claims.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1-9 and 12-20 remain rejected in the alternative, under 35 U.S.C. 103(a) as obvious over Denzinger et al. (US 4,402,937).

The prior art reference is discussed above. The prior art reference discloses PVP K-values of from 8 to 50 and these values are within the range claimed in claims 1, 6, 13-15, and 17-19 by applicants. The prior art discloses that the PVP-iodine solution prepared is about 50% higher in stability than that of the PVP-iodine solutions that have been previously prepared according to the previous state of the prior art (column 4, lines 44-48). Formic acid is the reducing agent and meets claims 3-5. The temperature at which Denzinger carries out its reaction (70, 75, 80 degrees C., see above for discussion of Denzinger) and the times (5, hours, 20 hours and 2 hours) meet the temperature and time requirement of claim 2. The 10-60% PVP aqueous solution meets claims 1, 6, 8, 14, 16, 18 and 20. 6% iodine is at least 4% and meets claim 1 and 7. The prior art fails to exemplify the claimed relationship. A review of the records does not establish relationship of the starting concentration of the PVP and reaction time for the preparation of the PVP-iodine on the stability of the PVP-iodine in aqueous solution. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a PVP-iodine solution according to the process of Denzinger where the PVP-iodine solution is more stable than the PVP-iodine solution prepared as per the state of the prior art. One having ordinary skill in the art would have been motivated to optimize the starting concentration of the PVP by routine experimentation that would be expected to produce a PVP-iodine solution that is at least 50% higher in stability than that of the state of the prior art.

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A rejection above is made under 35 USC 102 and in the alternate under 35 USC 103.

The reason for the alternative rejection under 35 USC 102/103 is that the claimed invention reads on the disclosure of the prior art but because the prior art does not teach the recited relationship between concentration, the cited relationship being a characteristic, which the K value of PVP is a value that would characterize all PVPs except shown otherwise that the particular relationship recited in claim 1 is unique only to the claimed PVP solution. MPEP 2112 [R-3] III states that rejection under 102/103 is proper when process is claimed in terms of function, characteristic or properties.

### *Response to Arguments*

7. Applicant's arguments filed 1/25/07 have been fully considered but they are not persuasive.

Applicant argues that Denzinger cannot anticipate the claims because, as admitted by the examiner, Denzinger does not teach the recited relationship. That Denzinger does not suggest or imply that the concentration or the K value has impact on the stability of the product; and that the examiner's position that the ordinary skilled artisan would have been motivated to optimize the starting concentration of the PVP by routine experimentation is in error.

Response:

The equation in claim 1 is applicable to range of K values and a range of concentrations "c" and the equation does not represent a single point, because if it did, then, a single point expression is all that would have been needed. Different concentrations would be obtained

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when the claimed range of K values of from 10 to 100 are plugged into the equation. Denzinger discloses K values of from 8 to 50 as described above in the rejection and this range falls within the claimed range of 10 to 100 for the K values. The K values for PVP are known quantities and the prior art disclosure of K values for the PVP is a recognition of the existence of K values for PVP and a silence of the art in relating K values and concentrations to stability is not an indication by the art that concentration and K values are not related to stability. The starting amount of 6% for the iodine in the Denzinger art is at least 4.0%. Secondly, the interpretation that an equation is not a single point is supported by claims 13-20, which claim different concentrations relating to different K values. Therefore, the rejection is not in error.

8. The declaration under 37 CFR 1.132 filed 1/25/07 is insufficient to overcome the rejection of claims 1-9 and 12-20 based upon the rejections under 35 USC 102(b) and 35 USC 103 as set forth in the last Office action because:

A) Regarding the rejection and the K values and the c, an equation sets forth variables that meet certain criteria when certain conditions are met in order to make the equation a valid representation of the process or parameters the equation is attempting to address. Thus applicants declaration that the prior art uses different concentrations in relation to different K values is validated by the claims 13-20 in which, different concentrations of PVP have different K values.

B) Regarding the working examples in Denzinger vs. equation in claim 1, it is noted that the equation supports a variation of K values and concentrations and the examples in Denzinger and instant claims 13-20 support variation of K values and concentration. Denzinger uses aqueous PVP solutions in the same way as applicant uses aqueous PVP solutions.

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C) With respect to the use of PVP concentration above the calculated minimum concentration according to equation in claim 1, it is noted that claim 1 starts with at least 4% iodine and Denzinger similarly starts with at least 4% iodine and K values of 8-50 for PVP that falls within the claimed K values of 10-100. Denzinger starts with aqueous PVP solution of from 10-60% and starting concentration fall in the range of the starting concentrations in applicant's data. The data presented does not have comparable data from Denzinger. No comparison with Denzinger is provided to demonstrate that applicant's PVP-iodine solution is more stable. For example, in Example 3, Denzinger uses 166 parts of the 50% PVP solution prepared according to A having a K value of 12.5; this 166 parts of 50% in the example 3 is no longer 50% after the addition of 0.75 parts formic acid and 17 parts iodine, thus the starting concentration is less than the 50% applicant assumes to be.

D) The declaration has not presented comparative data from Denzinger.

No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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